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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,834	04/24/2006	**Bernd Stahl**	0470-061191	2278

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,834	STAHL ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20-26 and 31-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 20-26 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/25/08 has been entered.

The following office action is a responsive to the Amendment filed, 08/25/08.

The amendment filed 08/25/08 affects the application, 10/576,834 as follows:

1. Claims 16, 31, 33, 34 have been amended. Claims 27-30 have been canceled. Applicant amendments have overcome the rejections made under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 103(a). Consequently, the said rejections are withdrawn. However, the rejections made under 35 U.S.C. 112, first paragraph is maintained and a new ground(s) rejection is set forth herein below.
2. The responsive to applicants' amendment and arguments is contained herein below.

Claims 16, 20-26 and 31-39 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 20-26 and 31-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy

Type 4 in a mammal, comprising administering the said given oligosaccharide composition, does not reasonably provide enablement for preventing said diseases or conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

> (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method for the treatment and or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of a given specific oligosaccharide composition.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating and/or preventing an immune system-related disorder selected from the group

consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in any mammal by administering a oligosaccharides composition to any mammal.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses the prevention the said diseases or conditions in any mammal, which are not known to have a single recognized cause. Applicants claims are drawn to a method for the prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal a specific oligosaccharide composition, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said diseases or conditions, which is seen to be lacking a clear description via art recognized procedural and methodological steps. For example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1

which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people. Similarly, the prevention of immunosenescence, acquired immunodeficiency syndrome and human immunodeficiency virus infection in a mammal comprising administering to said mammal a composition (wherein these said diseases or conditions are characterized as having several causes and contributing factors), is not generally known to exist in this art and is also rejected herein. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented.

Thus, the skilled artisan would view that the prevention of the said diseases or conditions (which is characterized as having many contributing factors and causes) in any mammal by administering to said mammal the specific composition herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary: Moreover, it is noted that the specification does not provide any working examples.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a

mammal, comprising administering to said mammal a specific oligosaccharide composition, in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of preventing said diseases or condition of any mammal as recited in the instant claims suitable to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, the prevention allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal said specific oligosaccharide composition by said method is not enabled by the instant disclosure. It should be noted that claims 20-26 and 31-39 which are drawn to a method of preventing the said diseases are also encompassed by the aforementioned rejection.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20-26, 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikemizu et al. (JP 2003221339 A, Abstract) in combination with Okada et al. (EP 1321527 A1).

In claim 16, applicant claims a method for the treatment and/or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of an acid oligosaccharide and a neutral oligosaccharide, wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooliogosaccharides and mixtures thereof. Claims 20-24, 31-39 are drawn to the said method wherein acid and neutral oligosaccharides are of specific types, wherein the immune system-related disorder is a specific type including allergy types, wherein said method further comprises administering specific polyunsaturated fatty acid per day and wherein the composition comprises specific ingredients and are in specific food forms. Claims 25-26 are drawn to the said method wherein the composition is administered enterally and to humans of specific ages.

Ikemizu et al. disclose an anti-inflammatory agent useful as a pharmaceutical for treating atopic dermatitis that contains acidic xylo-oligosaccharide having uronic acid residue in

xylooligo sugar-molecule, as active ingredient (see abstract). Furthermore, Ikemizu et al. disclose that the acidic is a mixed composition of an oligosaccharide having average polymerization degree (differing from xylose) of 2.0-11.0 (see abstract).

The difference between applicant's claimed method and the method suggested by Ikemizu et al. is that Ikemizu et al. do not exemplify the administration of the their composition for treating an immune system-related disorder in a mammal and do not use a neutral oligosaccharide in their composition.

Okada et al. disclose that atopic dermatitis can be treated with an oligosaccharide raffinose (an α-galactosyl oligosaccharide or neutral oligosaccharide) (see col. 3, paragraph [0014]). Furthermore, Okada et al. disclose that allergic disease such as atopic dermatitis can be treated with an oligosaccharide containing α-galactosyl (an α-galactosyl oligosaccharide or neutral oligosaccharide) (see page 19-20, paragraphs [0108]-[0109]). In addition, Okada et al. disclose that their composition can be as pharmaceutical or as a functional food material (see page 19-20, paragraphs [0108]-[0109]).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Ikemizu et al. and Okada et al, to treat atopic dermatitis (a Type 1 allergy) in an a mammal by administering to said mammal a composition comprising a combination of Ikemizu et al.'s acid oligosaccharide and Okada et al's neutral oligosaccharide, since the combination of compounds that are used to treat the same diseases or conditions are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Ikemizu et al. and Okada et al., to treat atopic dermatitis (a Type 1 allergy) in an a mammal by administering to said mammal a composition comprising a combination of Ikemizu et al.'s acid oligosaccharide and Okada et al's neutral oligosaccharide, since a skilled artisan would reasonable expect to use a composition comprising the combination of the compounds taught by Ikemizu et al. and Okada et al. for the same said purpose. It should be noted that the use of specific routes of administration such as enteral administration depends on factors such as the severity and location of the condition or disorder treated, the type, age and size of mammal. Also, it should be noted that the use specific food compositions, is also encompassed by this rejection since applicant's composition contains the same oligosaccharides and since the preparation of food compositions including the food composition suggested by Okada et al. is common in the art and is well within the purview of a skilled artisan and depends on factors such as the type, age of the individuals to whom the composition is be administered.

Response to Arguments

Applicant's amendments have not overcome the enablement rejections pertaining to prevention of the specifically recited diseases by administering said oligosaccharide composition, as set forth above. Applicant's arguments with respect to the rejections of claims 16, 20-26 and 31-39 made under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues that the specification admittedly enables the treatment of allergies. This, in turn, is recognized within the art as a means of lowering the risk and preventing the recited allergies. However, the lowering of risk does not equate to the prevention of allergies as

recited. That is, the reduction of risk factors is not a prevention of, not a predictor of nor a cure for any diseases or condition. Also, a treatment of allergies is not recognized within the art as a means of lowering the risk and preventing the recited allergies, as argued by applicant. It should be noted that treating of allergies after it occurs is not a preventive method and does not prevent the allergies from recurring. Moreover and as example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people (see also the above rejection).

The applicant argues that the invention prevents allergies by maintaining or restoring the Thl/Th2 balance (specification a page 4, lines 1-3). Therefore, Applicants have provided, at least in theory (which Applicants do not intend to be bound by), a description of how allergies can be prevented. However, maintaining or restoring the Thl/Th2 balance does not equate to the prevention of allergies. Moreover and as example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and

allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people. It should also be noted that the abstract submitted by applicant (see also the above rejection).

The applicant argues that the abstract "Prevention of early atopic dermatitis by an infant formula supplemented with immunoactive prebiotics in low atopy risk infants," Abstract for the 27th EAACI Congress, June 7-11, 2008) indicates that allergies can be prevented. On the contrary however, and as example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people (see also the above rejection).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
November 6, 2008.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623